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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,659	11/25/2003	Peter James Dunn	PC10383B	8807
28523	7590	08/18/2004	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			MCKENZIE, THOMAS C	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/723,659	Applicant(s) DUNN ET AL.	
	Examiner Thomas McKenzie, Ph.D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-43 is/are rejected.
- 7) ☒ Claim(s) 44 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/886,269.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/25/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to an application filed on 11/25/03. There are twenty-nine claims pending and twenty-nine under consideration. Claims 38-45 are compound claims. Claims 17-37 are method of making claims. This is the first action on the merits. The application concerns some processes of making Sildenafil and intermediates therefor.

Priority

2. The status of non-provisional parent application should also be included. Since the parent application has become a patent, please update the first line of the specification with the expression "now Patent No. 6,667,398" following the filing date of the parent application.

Claim Objections

3. Claim 27 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim because reference to two sets of claims to different features is not permitted. See MPEP § 608.01(n). The Examiner suggests adding the structure of compound VA.

4. Claim 28 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim because reference to two sets of claims to different features is not permitted. See MPEP § 608.01(n). The Examiner suggests adding the structure of compound VD.

5. Claim 29 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim because reference to two sets of claims to different features is not permitted. See MPEP § 608.01(n). The Examiner suggests adding the structure of radical R^d.
6. Claim 31 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim because reference to two sets of claims to different features is not permitted. See MPEP § 608.01(n). The Examiner suggests adding the structure of radicals A, G, and R³.
7. Claim 35 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim because reference to two sets of claims to different features is not permitted. See MPEP § 608.01(n). The Examiner suggests adding the structure of compound VII.
8. Claim 38 is objected to because of the following informalities: It is a compound claim, yet it depends upon a method claim. Appropriate correction is required. The Examiner suggests adding the structure of compound II.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Throughout these claims, Applicants use the term "general formula". This is indefinite because it implies more than one formula is claimed. The Examiner suggests deleting the word "general".

10. Claims 17-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Concerning formula II, in claims 17 and 26, Applicants have the limitation, "wherein R^X is a group substitutable by an aminopyrazole". In the passage spanning line 21, page 9 to line 11, page 10, Applicants provide an open definition of this term. In addition to the radicals listed in the passage discussed, what else is being claimed? The Examiner suggests either listing the claimed radicals or amending the specification to make clear what is being claimed.

11. Claims 17-25, 30, 31, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Concerning formula IV, Applicants have the limitation, "G represents *** or a derivative thereof." In the passage spanning line 21, page 11 to line 16, page 12, Applicants

scm

provide an explanation, using open terms, of which derivatives they intended. In addition to the radicals listed in the passage discussed, what else is being claimed? The word "derivatives" is indefinite for we do not know which compounds are contemplated. A derivative is the result of a reaction upon an organic molecule. Since we do not know the reagents or the conditions of these reactions, there is no way of determining the structures of the claimed "derivatives". The phrase "derivatives thereof" is, in essence, a product by process claim. Yet Applicants have not described the intended processes sufficiently that we may understand the structures of the compounds they claim. Webster's New World Dictionary defines derivative as "a substance derived from ... another substance by chemical change", and "substitution of one or more elements or radicals for one or more constituents of the original substance" has occurred. All implying that new chemical bonds have formed. The Examiner suggests either listing the claimed derivatives or amending the specification to make clear what is being claimed.

12. Claims 17-25 and 30-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the final two lines of claim 17, Applicants have the limitation, "with an appropriate reagent for converting the group G to a $-C(RX)=NH$ group". In the passage spanning line 17,

page 12 to line 4, page 16, Applicants give examples of such reagents using the open term "for example". In addition to the reagents listed in the passage discussed, what else is being claimed? The Examiner suggests either listing the claimed radicals or amending the specification to make clear what is being claimed.

13. Claims 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the final line of claim 26, Applicants have the limitation, "with a reagent that will convert one RX group to another". In the passage spanning line 6, page 16 to line 14, page 17, Applicants give examples of such reagents using the open term "for example". In addition to the reagents listed in the passage discussed, what else is being claimed? The Examiner suggests either listing the claimed radicals or amending the specification to make clear what is being claimed.

14. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the final line of the claim, "with a reagent that may be used for the introduction of a SO_2L^1 group into an aromatic or heteroaromatic ring system". In the passage spanning line 19, page 18 to line 25,

page 18, Applicants give examples of such reagents using the open term "for example". In addition to the reagents listed in the passage discussed, what else is being claimed? The Examiner suggests either listing the claimed radicals or amending the specification to make clear what is being claimed.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

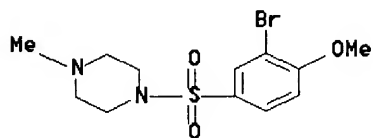
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

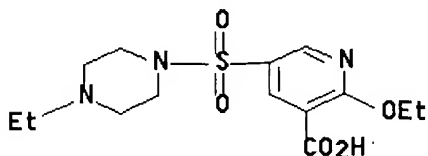
Claim 41 is rejected under 35 U.S.C. 102(b) as being anticipated by Dunn (EP 812,845 A1, cited by Applicants). The compound (V) fits formula (IV) with A = CH, R³ = ethyl, G = CO₂H, and R⁴ = methyl. It is found in the scheme on page 5 of the reference. Compound (II) on the same page also anticipates as a derivative of the claimed carboxylic acid.

16. Claim 41 is rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (Synlett). The compound shown below fits formula (IV) with A = CH, R³ = methyl, G = bromine, and R⁴ = methyl. A bromine atom attached to a benzene ring may be converted to a carboxylic acid by exchange with butyl lithium and reaction with CO₂. Conversely, a bromine atom attached to a benzene ring may be prepared from a carboxylic acid by a Hunsdiecker reaction. Thus, it is a "derivative". It has

registry number 215187-22-7 and is found in the Table 1 on page 1025 of the reference. Compound 11 was prepared from this substance. Although the reference does not tell how the bromo compound was prepared, there is no doubt Johnson (Synlett) possessed the compound shown. The compound 11 in the reference, with $A = \text{CH}$, $R^3 = \text{methyl}$, $G = \text{N-(BOC)-pyrrol-2-yl}$, and $R^4 = \text{methyl}$ also anticipated applicants' claim since for all the Examiner knows, a pyrrolyl group is also a "derivative" of CO_2H .



17. Claims 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Bunnage (WO 99/54333 A1). The compound shown below fits formula (IV) with $A = \text{N}$, $R^3 = R^4 = \text{ethyl}$, and $G = \text{CO}_2\text{H}$. It has registry number 247582-73-6 and is found in lines 10-24, page 127 of the reference. The ethyl ester is found in lines 1-9, page 125. Thus, claim 43 is anticipated.



Allowable Subject Matter

18. Claims 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 17-40 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion


19. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

20. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (703)

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872-9306. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


Thomas C. McKenzie, Ph.D.
Patent Examiner
Art Unit 1624

TCMcK/me